

1 PUBLIC PROTECTION CABINET

2 Kentucky Department of Insurance

3 Agent Licensing Division

4 (New Emergency Administrative Regulation)

5 806 KAR 9:360E. Pharmacy Benefit Manager License.

6 RELATES TO: KRS 304.1-050, 304.9-053, 304.9-054, 45 C.F.R. 156.122

7 STATUTORY AUTHORITY: KRS 304.2-110, 304.9-053(2), 304.9-054(6)

8 NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.2-110 provides that the

9 Commissioner of Insurance may make reasonable administrative regulations necessary for or as

10 an aid to the effectuation of any provision of the Kentucky Insurance Code. KRS 304.9-053(2)

11 requires a pharmacy benefit manager seeking a license to apply to the commissioner in writing

12 on a form provided by the department. KRS 304.9-054(6) requires the department to promulgate

13 administrative regulations to implement and enforce the provisions of KRS 304.9-054, 304.9-

14 053, 304.9-055, and 304.17A-162. This administrative regulation establishes requirements for

15 the licensure of pharmacy benefit managers.

16 Section 1. Definitions.

17 (1) "Commissioner" is defined by KRS 304.1-050(1).

18 (2) "Department" is defined by KRS 304.1-050(2).

19 (3) "Maximum allowable cost" is defined by KRS 304.17A-161(3).

20 (4) "Pharmacy benefit manager" is defined by KRS 304.9-020(15) .

21 Section 2. Initial License and Renewal.

(1) An applicant for a pharmacy benefit manager license or renewal license from the commissioner shall submit the following in hard copy format to the department:

(a) The Pharmacy Benefit Manager License Application;

(b) The fee set forth in KRS 304.9-053(3) and the penalty fee, if applicable, set forth in KRS 304.9-053(5);

(c) The following evidence of financial responsibility:

1. The certificate of an insurer authorized to write legal liability insurance in this commonwealth, stating that the insurer has and will keep in effect on behalf of the pharmacy benefit manager a policy of insurance covering the legal liability of the licensed pharmacy benefit manager's erroneous acts or failure to act in his or her capacity as a pharmacy benefit manager, and payable to the benefit of any aggrieved party in the sum of not less than one million dollars (\$1,000,000); or

2. A cash surety bond issued by a corporate surety authorized to issue surety bonds in this commonwealth, in the sum of one million dollars (\$1,000,000), which shall be subject to lawful levy of execution by any party to whom the licensee has been found to be legally liable;

(d) The name of at least one (1) responsible individual who shall be responsible for the pharmacy benefit manager's compliance with the insurance laws and administrative regulations of this state and who is:

1. Licensed as an administrator in Kentucky; and

2. Designated in accordance with KRS 304.9-133;

(e) If performing utilization review in accordance with KRS 304.17A-607, the pharmacy benefit manager's utilization review registration number;

(f) The following written policies and procedures to be used by the pharmacy benefit manager:

1. Appeals dispute resolution process;
2. Maximum allowable cost appeals process;
3. Exceptions policy and override policy required by 45 CFR 156.122(c) and KRS 304.17A-163 and KRS 304.17A.165; and
4. Pharmacy and Therapeutics committee membership standards and duties as required by 45 C.F.R. 156.122(a); and

(g) Proof of registration with the Kentucky Secretary of State.

(2)(a) Upon receipt of a complete application as required by subsection (1) of this section, the commissioner shall review the application and

- 1.a. Approve the application; and
- b. Issue the applicant the pharmacy benefit manager license;
2. Notify the applicant that additional information is needed in accordance with paragraph (b) of this subsection; or
3. Deny the application in accordance with paragraph (c) of this subsection.

(b)1. If supplemental or additional information is necessary to complete the application, the applicant shall submit that information within thirty (30) days from the date of the notification from the commissioner.

2. If the missing or necessary information is not received within thirty (30) days from the date of the notification, the commissioner shall deny the application unless good cause is shown.

(c) If the commissioner determines that the applicant does not meet the requirements for licensure, or if the application is denied pursuant to paragraph (b)2. of this subsection, the commissioner shall:

1. Provide written notice to the applicant that the application has been denied; and
2. Advise the applicant that a request for a hearing may be filed in accordance with KRS 304.2-310.

(4)(a) Except as provided in paragraph (b) of this subsection, a pharmacy benefit manager license shall:

1. Be renewed annually as required by subsection (5) of this section; or
2. Expire on March 31.

(b) If the license was issued on or before January 1, 2017, the license shall expire on March 31, 2018, if not renewed as required by subsection (5) of this section.

(5)(a) A renewal application shall include the items required by subsection (1) of this section.

(b) If the renewal application is submitted between April 1 and May 31, the application required by subsection (1) of this section shall be accompanied by a penalty fee of \$500 in accordance with KRS 304.9-053(5).

Section 3. Notice of Changes. Within thirty (30) days of any change, a licensee shall notify the commissioner of all changes among its members, directors, officers, and other individuals designated or registered to the license, and any changes to its written policies and procedures submitted pursuant to Section 2(1)(f) of this administrative regulation.

Section 4. Incorporation by Reference. (1) "Pharmacy Benefit Manager License Application", Form PBM, 09/2016, is incorporated by reference.

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2 law, at the Kentucky Department of Insurance, 215 West Main Street, Frankfort, Kentucky
3 40601, Monday through Friday, 8 a.m. to 4:30 p.m.